

REMARKS

The Present Invention

The present invention is directed to a method of inducing an immune response against an antigen in a mammal by inoculating the mammal with two different vectors encoding the antigen.

The Pending Claims

Claims 1-8, 21 and 22 are currently pending. All claims are directed to the method.

The Amendments to the Claims

Claims 1, 5, 21 and 22 have been amended to point out more clearly and claim distinctly the subject matter of the invention. Thus, no new matter has been added through amendment of the claims.

The Final Office Action

Claims 1-8, 21 and 22 have been rejected under 35 U.S.C. § 112, first and second paragraphs, and under 35 U.S.C. § 103. Reconsideration of these rejections is hereby requested.

Discussion of Rejection under 35 U.S.C. § 112, first paragraph

Claims 1-8, 21 and 22 have been rejected under Section 112, first paragraph. While the Office admits that the specification enables a method of inducing a CTL response in a mammal comprising administering various viral vectors comprising a nucleic acid insert encoding an antigen operably linked to a promoter, the Office apparently is under the mistaken impression that the instant specification does not recite a method of inducing a CTL response in a mammal as a utility. The Office contends that the only stated utility is inducing a therapeutic or prophylactic immune response against an antigen. Based on such contention, the Office concludes that the utility of inducing a therapeutic prophylactic immune response is not reasonably enabled by the instant specification. The rejection is traversed for the reasons set forth below.

Applicants respectfully submit that the specification discloses that the method of administering viral vectors encoding an antigen can be used to induce a CTL response in a mammal (see the specification at, for example, page 6, lines 21-23 and 27-33 et seq.). The language of the claims is consistent with the utility set forth in the instant specification inasmuch

as the claims recite "[a] method for inducing an immune response against at least one antigen in a mammal . . ." According to the M.P.E.P. at § 2164.08, the only relevant concern regarding the breadth of a claim relevant to enablement should be whether the scope of enablement provided to one skilled in the art is commensurate with the scope of protection sought by the claims. In this regard, the Office has admitted that the utility stated in the specification and recited in the claims is enabled by the instant specification. Accordingly, Applicants respectfully request withdrawal of the rejection under Section 112, first paragraph, for alleged lack of enablement.

Discussion of Rejection under 35 U.S.C. § 112, second paragraph

Claims 1-8, 21 and 22 have been rejected under Section 112, second paragraph, as allegedly indefinite for failing to point out particularly and claim distinctly the subject matter of the invention. Applicants respectfully disagree with this rejection. However, in order to expedite prosecution of this application and not in acquiescence of the rejection, Applicants have amended claim 1. Method step "(i)" of amended claim 1 replaces the phrase "at least one" antigen with "an" antigen, which provides an antecedent basis for the term "said" antigen, which replaces "at least one" antigen, in method step "(ii)" of amended claim 1, wherein method step "(ii)" is directed to the second recombinant vector. The amendment of claim 1 is believed to clarify that the induced immune response is directed towards the same antigen, which is encoded on both of the first recombinant vector and the second recombinant vector. As suggested by the Office, claims 5, 21 and 22 have been amended to recite that the insert of the first recombinant vector and the insert of the second recombinant vector encode the same antigen.

In view of the foregoing, Applicants submit that claims 1-8, 21 and 22 are definite. Accordingly, Applicants respectfully request withdrawal of the rejection under Section 112, second paragraph.

Discussion of Rejection under 35 U.S.C. § 103

Claims 1-3 and 5-7, have been rejected under Section 103 as allegedly obvious in view of and, therefore, unpatentable over Wang (J. Immunol., (1995 May 1) 154 (9): 4685-92). This rejection is traversed for the reasons set forth below.

Applicants respectfully submit that claims 1-3 and 5-7 are not obvious in view of Wang, since Wang does not teach inducing an effective immunological response by inoculating with different vectors encoding the same antigen, as does the present invention. The Office contends that one of ordinary skill in the art at the time the invention was made would have been motivated to replace the wild-type vectors used in Wang with the recombinant FPV (fowlpox virus) or VV (vaccinia virus) vectors presented in the instant application. However, no motivation or suggestion to induce an immune response in a mammal by administering two different, recombinant vectors encoding the same antigen can be found in Wang.

In order to show that a motivation or suggestion to produce the claimed invention is implicit in the prior art, the Office must show what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art. *See In re Lee*, 277 F.3d 1338, 1342-44 (Fed. Cir. 2000). The Office cannot simply assert that those of ordinary skill in the art would have been motivated to make the claimed invention based on the knowledge in the art at the time the application was filed. Rather, the Office must provide objective evidence of the knowledge in the art at the time by providing specific factual findings indicative of such. *See Id* and M.P.E.P. § 2142.

Applicants point out that the Office has failed to meet its burden for establishing a *prima facie* case of obviousness since it has not presented the requisite specific factual findings to establish the level of knowledge in the art that is to be combined with Wang to establish the obviousness of the claimed invention. The Office merely alleges on page 9 of the Office Action that "motivation to replace wild-type FPV with FPV-β-gal comes from the knowledge of one of ordinary skill in the art at the time the invention was made . . ." Without specific factual findings establishing the level of knowledge in the art at the time the application was filed, it is impermissible for the Office to rely on any alleged implicit teachings of Wang in an attempt to establish the requisite motivation for an obviousness rejection.

The Office also contends that, although Wang did not teach administering two different vectors, both of which encode the same antigen, Wang did teach all of the limitations claimed in the application. In response Applicants direct the Office's attention to amended claim 1 of the application, which recites, "the first recombinant vector is different from the second recombinant vector." The use of two different recombinant vectors, each of which encodes the same antigen, is an essential limitation of this invention neither taught nor rendered

obvious by Wang. Thus, it is improper to assert that all claimed limitations of this application are taught by Wang, particularly when the Office, itself, states the opposite, at, for example, page 9 of the Office Action.

Additionally, Wang teaches away from the use of rVV at, for example, page 4690, col. 2, paragraph one. Wang states that " [a]nother significant problem associated with rVV-based vaccines is that they are replication competent in man and could pose the problem of disseminated viremia... ." According to the M.P.E.P. § 2145, a prior art reference that teaches away from the claimed invention is a significant factor in determining unobviousness. The claimed invention is directed to the use of rVV to administer a recombinant vector to a mammal, — precisely what Wang teaches away from. Thus, Wang, whether taken alone or in view of the state of the art, does not render the claimed invention obvious.

Finally, the claimed invention displays greater than expected results in view of Wang. For example, Fig. 5(B) of Wang depicts that mice treated with two doses of rFPV post-tumor challenge were dead by day 22. In the instant application at, for example, Fig. 1C, roughly 60% of mice immunized with rFPV and rVV (VJS6) survived over 110 days. Such results can be regarded as surprising and unexpected, and further evidence of the unobviousness of the present invention.

In view of the above, Applicants submit that claims 1-3 and 5-7 are not obvious. Therefore, Applicants respectfully request withdrawal of this rejection under Section 103 for obviousness.

Claims 1-3, 5-7, 21 and 22 have been rejected under Section 103 as allegedly obvious in view of and, therefore, unpatentable over Wang (J. Immunol., (1995 May 1) 154 (9): 4685-92). The Office contends that Wang taught administering rVV- β -gal to mice followed by rFPV- β -gal or *vice versa* to induce an immune response. Applicants direct the Office's attention to the preceding argument in opposition to this contention. Although Wang may have suggested using MART-1 and gp100 to make recombinant vectors, the method disclosed in Wang does not render obvious the methods of the instant invention as argued above, and therefore, this rejection for obviousness is moot in view of the preceding argument.

Claims 1-8 have been rejected under Section 103 as allegedly obvious in view of and, therefore, unpatentable over Wang (J. Immunol., (1995 May 1) 154 (9): 4685-92) in further view of Zhai (Jan. 15, 1996, J. Immunol., Vol. 156, No. 2, pages 700-710). Again,

In re Appln. of Chamberlain et al.
Application No. 09/838,987

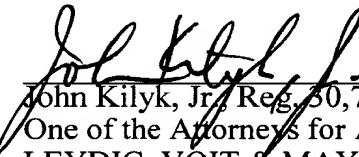
Applicants direct the Office's attention to the argument above, wherein Applicants establish that the claimed invention is not obvious in view of Wang. Zhai does not cure the deficiencies of Wang. Zhai merely teaches the administration of an adenoviral vector encoding β-gal. Zhai, alone or in combination with Wang, does not teach or suggest the administration of a recombinant vector to a mammal followed by administration of a second recombinant vector encoding an antigen from the first recombinant vector, wherein the second recombinant vector is different from the first recombinant vector. Thus, the obviousness rejection for Wang in view of Zhai cannot stand.

Conclusion

The application is considered to be in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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